REMARKS

Claims 1-16 are of record pending in this case and stand rejected. Claims 10-16 have been cancelled. Claims 17-19 are new. No other claims are currently added or canceled. Reexamination and reconsideration of claims 1-9 and 17-19 are respectfully requested.

Note, no new matter is believed to be added by any of the amendments hereof or herein. Moreover, any matter cancelled or otherwise no longer in the present claims due to amendment, cancellation or otherwise is intended to be so cancelled or otherwise outside the present scope without prejudice to potential pursuit through continuation or otherwise.

Information Disclosure Statement

Applicants hereby submit the attached Information Disclosure Statement and respectfully request consideration hereof.

Priority

Applicants note with appreciation the withdrawal of the objection to the specification in view of the Amendment of May 20, 2009.

Claim Objections

Applicants note with appreciation the withdrawal of the objection to claims 1, 10, and 13 in view of the Amendment of May 20, 2009.

Rejections Under 35 U.S.C. § 102(b)

Claims 10-11 stand rejected under 35 USC 102(b) as purportedly being anticipated by Mainelis et al. (Aerosol Science and Technology, 1999, vol. 30, pages 127-144, hereinafter "Mainelis 1999"). Claims 12-13 stand rejected under 35 USC 102(b) as purportedly being

anticipated by Mainelis et al. (Aerosol Science and Technology, 2002, vol. 36, pages 1074-1085; hereinafter "Mainelis 2002"). Claim 14 also appears to be rejected under 35 USC 102(b) in view of Mainelis 2002.

Applicants note that claims 10-16 have been cancelled by amendment herein. Thus, the rejection under 35 USC 102(b) no longer applies. Applicants submit that the present application is allowable, and action to this end is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1-13 stand rejected under 35 USC §103(a), as purportedly being unpatentably obvious over various applications of Birmingham et al. (U.S. Patent No. 5,989,824; hereinafter "Birmingham") in view of Mainelis et al. (Aerosol Science and Technology, 2002, vol. 36, pages 1074-1085; hereinafter "Mainelis 2002"), firstly, for claims 1-8; or over Birmingham in view of Mainelis 2002 and further in view of Johns, et al. (Letters in Applied Microbiology, 1994, vol. 18, pages 236-238; hereinafter "Johns") for claims 9-13. Claims 14-16 also appear to stand rejected in view of some combination of the above-mentioned references.

As a preliminary matter, Applicants note that claims 10-16 have been cancelled by amendment herein. Thus, the rejections under 35 USC 102(b) and 103 no longer apply to those claims.

Applicants incorporate by reference the arguments presented in Applicants' previous response to Office Action, dated May 20, 2009. Applicants hereinbelow address the remaining claims at issue, namely, with respect to claims 1-9.

Applicants' Developments

The currently claimed developments are structurally different from and yield unexpectedly improved properties or properties not present in the prior cited art, particularly as a result of the size of the sample chamber. Non-obviousness is demonstrated not only by the failure of the art to provide these specific combinations (not in/from Mainelis 2002,

Birmingham, nor Johns), but, also due to the otherwise unexpected and unpredictable properties reached therefrom. In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990). This showing of unexpected results is based on evidence presented in the specification. In re Mayne, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997). The presumption of obviousness will be rebutted if it can be shown: (1) That the prior art taught away from the claimed subject matter, In re Geisler, 116 F.3d 1465, 1471 (Fed. Cir. 1997); or (2) that there are new and unexpected results relative to the prior art, In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990).

Applicants have successfully reduced the size of their sample chamber to under 500 μL, as set forth in Applicants' claim 1. The Office Action of August 12, 2009, does not comment on this small size of the Applicants' present sample chamber (i.e., at most 500 μL) in making its 35 USC §103 rejections. Applicants have calculated the sample chamber size of the prior art and have come up with a volume of approximately 81,000 μL, i.e., more than 100 times greater than Applicants' sample chamber size.

None of Birmingham, Johns, or Mainelis 2002 disclose such sample chambers as small as Applicants' here. For an example, Birmingham is designed to be readily portable and carried about by an operator, suitable for possible use in a battlefield environment. Commenting on its scale, Birmingham notes that in a preliminary design, a video tape is used as a collection surface for the bacterial cells/spores; a typical video tape is approximately ½ inch wide, which together with the other requirements of Birmingham such as an electric motor and an impact absorbing plastic housing, would make a 500 μL chamber highly unlikely, and at least specifically not taught or suggested. Therefore, no combination of the above references would teach, suggest, or motivate using a small sample chamber of no more than 500 μL. The Office Action fails to discuss the absence of the 500 μL limitation in the prior art.

Applicants have also found, surprisingly in view of the art, that there are numerous benefits in the present developments that allow for performance of electrostatic collection of gas suspended particles in a sample chamber of at most 500 μL which are directly related to the scale.

First, the developments offer a better degree of concentration of the biological particles to be analyzed, due to the small volume of the sample chamber, a result not available to larger scale devices; size thus being directly related to functional advantage.

Also, due to the small volume of the sample chamber, and the high degree of concentration it affords, it becomes feasible to suspend the collected particles in a liquid and to perform analysis directly on this liquid without any of the time-consuming enrichment steps suggested in Mainelis 1999 or Mainelis 2002. Scale is directly related to this difference in processes.

The liquid handling of the present development also makes the analysis simpler, easier to control, and easier to integrate with other microsystem technologies.

Finally, another advantage of performing electrostatic collection of particles in a microscale sample chamber as claimed here is that the electrodes can be placed closer together than in the macroscale systems in the prior art. This reduces the power requirements of the power supply. These reduced power requirements allow for smaller power supplies, such as smaller batteries, which then results in systems having an improved portability. Another direct result of the scale difference.

Undue Experimentation and Incompatibilities between Birmingham and Mainelis 2002

There are critical incompatibilities between Mainelis 2002 and Birmingham that would hinder attempts to combine the two devices in a single device. Thus, it would not be obvious to try to combine the devices of Mainelis 2002 and Birmingham due to those incompatibilities.

The attempt to combine the devices of Mainelis 2002 and Birmingham would require undue experimentation, further inventive modification, and the use of hindsight, to arrive at Applicants' development. The disclosure in an asserted reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is

insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003).

Note, this concept of "undue experimentation" is substantially the same as that used for judging the enablement of an applicant's disclosure; and, on this, MPEP 2164.03 Relationship of Predictability of the Art and the Enablement Requirement is instructive. In particular, there it is noted that:

> in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. In re Soll, 97 F.2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d 1438, 1445 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work.

One example of such incompatibilities between Birmingham and Mainelis 2002 is that Mainelis 2002 teaches that an agar layer is necessary between the two electrodes. But Birmingham teaches that the particles are present on a metal coupon. What happens in combination, retain the agar or not?; this much is not taught and renders difficult if not possible the asserted combination of Mainelis with Birmingham. Furthermore, Birmingham teaches that the specimen is deposited on the metal coupon as a dry sample. Again, what about the Mainelis agar; can the dry system taught by Birmingham accept the agar? Still further, Birmingham teaches ionizing charges over the biological particles. It would be very difficult, if not impossible, to create useful ionizing charges in a controlled manner over the agar-covered electrode of Mainelis.

Moreover, neither Mainelis (1999 or 2002) nor Birmingham disclose a sample chamber having a volume of at most 500 μL, and a skilled person would deem it unlikely that a combination of the technologies disclosed in Birmingham or in Mainelis would work with in a

microscale system. For example, it is unclear how the agar of Mainelis should be deposited in the dry coupon system of Birmingham. There is also significant risk that the agar could clog up a micro-volume sample chamber as defined in the presently-claimed developments.

Finally, Birmingham generally relates to an apparatus for the lysing of bacterial cells or spores, which apparatus uses ionized **fluids, only exemplified by ionized gases**. Applicants' claim 1 includes the limitation, d, "contacting the biological particle collected in the sample chamber with a first liquid" (emphasis added).

There is a genus-species relationship between fluid (genus) and liquid (species). The use of gases, as in Birmingham, does not teach, suggest, or motivate use of a liquid. The Office Action agrees with Applicant in this regard, i.e. "As Applicants correctly argue, the term, "fluid", employed by Birmingham is not "liquid," but rather, gases." Office Action, p. 16, para. 3. Thus, Birmingham does not disclose contacting the collected biological particles with a **liquid**.

Contrary to the assertions of the Office Action, Birmingham does not disclose contacting the collected biological particles with a **liquid,** as suggested on page 16 of the Office Action. This is an affirmative element of the claims here and as such must not be ignored. Any claim interpretation which renders a claim term superfluous is disfavored. Stumbo v. Eastman Outdoors, Inc., 508 F.3d 1358, 1362 (Fed. Cir. 2007). Birmingham specifically states, teaches and suggests that the specimen there is deposited on the metal coupon as a dry sample in which the bacterial cells and/or spores collected from the ambient environment are concentrated. Col. 4, line 49.

On the other hand, the Office Action reasons that (a) Birmingham assertedly motivates one to collect/concentrate, lyse, and identify in the same space; (b) for the 'identification' process, Birmingham assertedly explicitly contemplates PCR; (c) thus, because PCR requires buffers and reagent mix, that one skilled in the art assertedly "would have recognized that the same space of Birmingham wherein the sample is collected/concentrated, lysed, and identified would have allowed liquid to be employed." Office Action, p. 16, para.s 5-7.

There are a number of reasons why Applicants disagree that this logic is accurate under the law of obviousness. Regarding (a), Birmingham alludes to the identification of spores without moving the coupon in the aspirational sense only, i.e. the invention 'is likely to be actually practiced', preferably 'without moving the coupon'. Birmingham, col. 4, lines 30-34. Birmingham does not enable such a method or device; i.e., does not point toward a technological solution to achieve same; nor does Birmingham teach in that direction as his conveyor is moving throughout his process. Stating an aspiration without enabling suggestion toward possible achievement is not enough; it would rather be more like saying something to the effect of wanting "smog-free air" – without more, this is not a true suggestion to a skilled artisan as to any particular combination of teachings to arrive at such. Moreover, no other art is cited to fill this void; aspiring toward a non-moving coupon is not the same as teaching or suggesting how it might be accomplished, and no art is cited for the asserted accomplishment. All elements must be in the cited art.

Regarding (b), Birmingham does not explicitly contemplate PCR, and at the least doesn't teach, suggest or motivate how such might be achieved in the moving dry coupon system thereof. Birmingham suggests, but does not explain or enable integration of, a number of alternatives to identifying the dry sample deposited on the metal coupon 20. These include a flight mass spectrometer, a bio-aerosol fluorescence sensor, and a pyrolysis-gas chromatography-ion mobility spectrometer, none of which appear to involve a liquid. The only mention of the PCR is several steps removed, in the Ebersole method, col. 5, line 27. This Ebersole device was disclosed as 'being developed', which indicates that it is/was not ready for use, much less incorporation into a present developments. Moreover, this method only contemplates first collection of the sample, "which is then amplified via PCR." This does not suggest that the PCR amplification would necessarily or even possibly take place on the same coupon, nor that it take place in "the same place." How would the liquid be added to the coupon; how would the PCR steps proceed on the coupon? Moreover, how would the non-enabled same place, non-enabled non-moving coupon work with this additional PCR concept, or would it? These are insufficiencies in how to teach the skilled artisan the asserted conclusion that liquid would be usable in/on the same coupon in a stationary manner. Indeed, it teaches away from the amplification step taking place within the same space as the concentration, collection, and lysis.

Thus, regarding (c) regardless of whether PCR uses buffers or reagent mix, there is no teaching, suggestion, or motivation in or from Birmingham that liquid be employed within the space where the sample is collected/concentrated, lysed, and analyzed. In short, this situation is not one of simple substitution, nor is it one of a simple 'upgrade'. See, cf., KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398 (2007) (discussing 'upgrading Asano with a sensor'). Applicants' presently claimed developments involve a combination, not subject to nor being a simple addition, replacement, mounting or an upgrade from Birmingham.

Neither Birmingham nor Mainelis 2002 disclose contacting the collected biological particles with a liquid, much less the type of liquid listed in Applicants' specification. The combination of these documents therefore cannot lead one skilled in the art to the present development. Thus, neither Birmingham nor Mainelis 2002 teach, suggest or motivate contacting the collected biological particles with a liquid, in the manner presented by Applicants, and the combination of these documents therefore cannot lead the skilled artisan to the present invention.

Still moreover, Birmingham's various elements are structurally distinct from Applicants'. Birmingham's description of the metal coupon (20) does not contain any indication that the coupon forms part of the spore collector or concentrator. In fact, Birmingham states that "The bacterial spores and/or cells separated from the air stream are then deposited as a specimen 22 on a metal coupon 20 that is disposed **adjacent** to spore collector and concentrator 18", col. 4, lines 10-11. This use of the term "adjacent" reads as "next to", not "part of".

This is different than Applicants' developments, and this difference is important to highlight in response to the Office Action characterization that the interior of the "spore collector and concentrator" (which is termed the "sample chamber") is the same as the coupon. For example, the Office Action, in the first line of page 10, defines the sample chamber as the interior of the sample collector and concentrator. Further down on page 10, in step c), it states "*c) exposing said liquid agent to an electric field in the* ***sample chamber…***", but there is no disclosure in Birmingham which discloses an electric field inside the sample collector and concentrator. Again, this differs from Applicants' microscale sample chamber.

Contrary to the assertions of the Office Action, Birmingham does not teach, suggest, or motivate the combination with Mainelis or with Johns and consequently does not provide a proper basis for rejection under section 103, whether on its own or in view of Mainelis, alone or together with Johns. It is therefore clear that the presently-claimed subject matter is non-obvious in view of the prior art of Birmingham. Moreover, Mainelis 2002 and Johns do not cure these failures of Birmingham (and indeed are not asserted for such purposes), and thus, the present claims are allowable over any of the purported combinations of these references.

The rejections of claims 1-9 are thus obviated and/or traversed and can and should be withdrawn. Action to this end is respectfully requested.

Double Patenting – Obviousness Type

Applicants note the provisional double-patenting rejections of the current claims over the claims of two co-pending applications. Applicants agree that these claims are not identical, but do not agree that they are obvious in view of each other, one way or the other. However, in the interests of speedy prosecution, and not in admission of any obviousness one way or the other, Applicants hereby file duly signed Terminal Disclaimers to obviate these rejections. These rejections may now properly be withdrawn.

CONCLUSION

Applicants note that all rejections are obviated or traversed and respectfully request that they thus be withdrawn. A timely Notice of Allowance is requested to be issued in this case. Applicants believe that no fees or petitions, other than the request for examination fee and the extension fee/petition set forth above, are due with this filing. However, should any such fees or petitions be required, please consider this a request therefore and authorization to charge Deposit Account No. 02-2093 as necessary.

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Respectfully submitted,

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